Illustration 1: Ensuring your face is clean

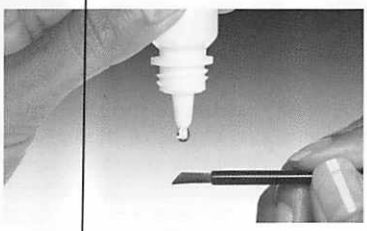

Illustration 2: Properly applying the drop to the unmodified applicator

Illustration 3: Applying LATISSE® to the upper eyelid margin using the unmodified applicator provided

Illustration 4: Blotting any excess solution

Illustration 5: Dispose of the applicator

DO NOT APPLY in your eye or to the lower lid. ONLY use the sterile applicators supplied with **LATISSE®** to apply the product. **Do not reuse or modify applicators and do not use any other brush/applicator to apply LATISSE.®** Fifty percent of patients treated with **LATISSE®** in a clinical study saw significant improvement by 2 months after starting treatment.

If **LATISSE®** solution from a single dose gets into the eye, it is not expected to cause harm. Don't allow the tip of the bottle or applicator to contact surrounding structures, fingers, or any other unintended surface in order to avoid contamination by common bacteria known to cause infections.

Use of **LATISSE®** more than once a day is not expected to increase the growth of eyelashes more than use once a day.

LATISSE® contains a preservative called benzalkonium chloride which may discolour soft contact lenses if the eye is exposed. If you wear contact lenses, remove them before using **LATISSE.®** They may be reinserted 15 minutes after **LATISSE®** application. Always use **LATISSE®** exactly as your doctor has instructed you.

Interactions with this medication:

No specific drug interaction studies have been done with this medication.

Overdose:

Overdosing (putting more than one drop on the applicator) may result in an increased chance of iris pigmentation (IP). Any extra solution outside the upper lid margin should be blotted with a tissue. If **LATISSE®** solution from a single dose gets into your eyes, **it is not expected to cause harm.**

In case of drug overdose, particularly accidental oral ingestion, contact a healthcare professional (e.g. doctor), hospital emergency department or regional poison control centre, even if there are no symptoms.

Missed dose:

If you miss a dose, don't try to "catch up." Just apply **LATISSE®** solution the next evening. Do not double dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, **LATISSE®** can have side effects. Most of the side effects are not serious.

The most common side effects after using **LATISSE®** solution are an itching sensation in the eyes and/or eye redness. This was reported in approximately 4% of patients. **LATISSE®** solution may cause other less common side effects which typically occur on the skin close to where **LATISSE®** is applied, or in the eyes. These include skin darkening, iris pigmentation, eye irritation, dryness of the eyes, redness of the eyelids.

If you develop a new ocular condition (e.g., trauma or infection), experience a sudden decrease in visual acuity (vision), have ocular (eye) surgery, or develop any ocular reactions, particularly conjunctivitis (eyelid infection) and eyelid reactions, you should immediately seek your physician's advice concerning the continued use of **LATISSE®** solution.

This is not a complete list of side effects. For any unexpected effects while taking LATISSE,® contact your doctor or pharmacist.

HOW TO STORE IT

LATISSE® should be stored in the original container at 2° to 25°C.

Do not use the drops after the expiry date (marked "Exp") on the bottle and the box.

Keep out of reach of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following three ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form, and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program
    Health Canada
    Postal Locator 0701C
    Ottawa, ON K1A 0K9

  Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada website at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found by contacting the sponsor, Allergan Inc., at: 1-800-668-6424.

This leaflet was prepared by Allergan Inc.

Last revised: January 07, 2013.

PART III: CONSUMER INFORMATION

PrLATISSE®
Bimatoprost Topical Solution 0.03% w/v
Sterile

This leaflet is part III of a three-part "Product Monograph" published when LATISSE® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about LATISSE.® Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
LATISSE® is used to treat hypotrichosis (less than normal hair) of the eyelash to increase the length, thickness and darkness of eyelashes.

What it does:
LATISSE® is believed to lengthen the growth period of your eyelashes and increasing the number of lashes involved in the growth phase. This results in longer, fuller and darker eyelashes.

When it should not be used:
LATISSE® should not be used if you are allergic to bimatoprost, to any of the other ingredients, or to any of the parts of the container (see What the non-medicinal ingredients are).

What the medicinal ingredient is:
Bimatoprost

What the non-medicinal ingredients are:
Benzalkonium chloride, as preservative; sodium chloride, sodium phosphate dibasic heptahydrate, citric acid monohydrate, and purified water. Sodium hydroxide and/or hydrochloric acid may be added to adjust pH.

What dosage forms it comes in:
Sterile solution containing 0.3 mg/mL bimatoprost, packaged as follows:

- 3 mL bottle of sterile solution with 60 accompanying sterile, disposable applicators.
- 5 mL bottle of sterile solution with 140 accompanying sterile, disposable applicators.

WARNINGS AND PRECAUTIONS

BEFORE you use LATISSE® talk to your doctor or pharmacist if:

- you have no visible eyelashes. Your doctor will consider any underlying conditions to determine whether this product is appropriate for you.
- you are taking, or have recently taken, any other medicines, including other bimatoprost products, or those not prescribed (see Interactions with this medicine). Use of **LATISSE®** in conjunction with other bimatoprost products may reduce the effectiveness of these products to lower intraocular eye pressure.
- you are pregnant or breastfeeding a baby. You should ask your doctor or pharmacist for advice before taking any medicine.
- you have an active eye infection or inflammation (e.g. uveitis), any other eye condition such as active eyelid disease, infection or broken or irritated eyelid skin or eye injury.
- you need to have eye surgery.
- you are allergic to bimatoprost, to any product ingredients, including benzalkonium chloride, or to any of the parts of the container.

LATISSE® solution is intended for use on the skin of the upper eyelid margins at the base of the eyelashes. Refer to Illustration 2 on reverse. **DO NOT APPLY to the lower eyelid.** If you are using **LUMIGAN®** or other products in the same class for elevated intraocular pressure (IOP), or if you have a history of abnormal IOP, you should only use **LATISSE®** under the close supervision of your physician.

LATISSE® use has been associated with iris pigmentation (pigmentation of the coloured part of the eye). This pigmentation is likely to be permanent. As overdosing (more medication than required) of **LATISSE®** may contribute to this pigmentation, it is extremely important to strictly observe the following measures:

- Do not apply directly in the eye.
- Do not add more than one drop to an applicator.
- Blot any excess solution outside the upper eyelid margin with a tissue or other absorbent material.
- Do not administer the medication more than once daily.
- Do not apply to the lower eyelash line.
- Do not use the same applicator for more than one eye.
- Do not reuse applicators.
- Do not alter the applicator in any form.
- Do not use any other brush/applicator to apply **LATISSE.®**

LATISSE® use may also cause darkening of the eyelid skin which may be reversible in most patients.

It is possible for hair growth to occur in other areas of your skin that **LATISSE®** frequently touches. Any excess solution outside the upper eyelid margin should be blotted with a tissue or other absorbent material to reduce the chance of this from happening. It is also possible for a difference in eyelash length, thickness, fullness, pigmentation, number of eyelash hairs, and/or direction of eyelash growth to occur between eyes. These differences, should they occur, will usually go away if you stop using **LATISSE.®**

Application of **LATISSE®** may temporarily blur your vision. Do not drive or use machines until your vision has cleared.

PROPER USE OF THIS MEDICATION

Usual adult dose:
The recommended dosage is one application nightly to the skin of the upper eyelid margin of each eye at the base of the eyelashes only.

Once nightly, start by ensuring your face is clean, makeup and contact lenses are removed **(see Illustration 1)**. Remove an applicator from its tray. Then, holding the sterile applicator horizontally, place ONLY one drop of **LATISSE®** on the area of the applicator closest to the tip but not on the tip **(see Illustration 2)**. Then immediately draw the applicator carefully across the skin of the upper eyelid margin at the base of the eyelashes (where the eyelashes meet the skin) going from the inner part of your lash line to the outer part **(see Illustration 3)**. **Blot any excess solution beyond the eyelid margin (see Illustration 4).** Dispose of the applicator after one use **(see Illustration 5)**.

Repeat for the opposite upper eyelid margin using a NEW sterile applicator. This helps minimize any potential for contamination from one eyelid to another.